the record. A copy of the report will be provided to the local station manager of the air carrier concerned at the close of each tour or not less frequently than each 24 hours.

(b) *Carrier conferences.* At least one a month, postal officials will schedule meetings with the local representatives of the affected air carriers to discuss the reported irregularities. The carrier's representative will be advised of any irregularity for which the reporting authority will recommend penalty action. The carrier's representative will be offered the opportunity to comment on any irregularity, and any comments will be attached and/or be made part of the record. The reports on which penalty action is recommended will then be processed by International Network Operations, Postal Headquarters.

(c) *Review, investigation, penalty action.* International Network Operations will review the matter and advise the carrier of the recommendations. The carrier has 21 days from receipt of notice to dispute the recommended penalties. In those instances which the carrier has disputed the facts alleged by the reporting authority, International Network Operations will investigate the matter to resolve the differences. International Network Operations, upon review of the record, may impose a fine or penalty against an air carrier for any irregularity properly documented, whether or not penalty action has been recommended. International Network Operations will send the decision, including notice of the irregularities alleged and the amount of fine or penalty proposed to the carrier. The Postal Service may, in its discretion, deduct from payment otherwise due the air carrier an amount necessary to satisfy the penalty action taken under this section.

(d) *Appeal.* If the final decision includes a penalty, International Network Operations will advise the carrier that it may, within 30 days, appeal the action in writing to the Vice President, Network Operations Management, Postal Headquarters, and that its written appeal should include all facts and arguments upon which the carrier relies in support of the appeal. If an appeal is not received, International Network Operations will close the file. When an appeal is taken, the Vice President, Network Operations Management, will review the complete record and decide the appeals. He will advise the carrier of the decision in writing and will take action consistent with that decision. The Vice President, Network Operations Management, may sustain, rescind, or compromise a fine or penalty. The decision of the Vice President, Network Operations Management, on appeal shall be the final decision of the Postal Service. The Postal Service, may, in its discretion, deduct from pay otherwise due the air carrier an amount necessary to satisfy the penalty action taken under this section.

(e) *Details of administration.* For further administrative details, forms, and other implementing materials adapted to the respective modes of transportation, see International Mail Operations, Handbook T–5, chapter 5.

§ 927.3 Other remedies.

The procedures and other requirements of this part apply only where the Postal Service proposes to assess penalties, fines, deductions, or damages. This part does not limit other remedies available to the Postal Service, including such remedies as summary action to withhold tender of mail to protect the public interest in the event of major irregularities such as theft, deliberate loss, damage, abandonment of the mail or service failures by the air carrier.

Stanley F. Mires,

Chief Counsel, Legislative.

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BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0158; FRL–7188–7]

Fludioxonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on bushberry subgroup, caneberry subgroup, fruit, stone, group, juneberry, lingonberry, pistachio, salal, and watercress. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 2, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0158 must be received on or before October 1, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0158 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://

www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0158. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of March 29, 2000 (65 FR 16602) (FRL–6495–5) and May 1, 2002 (67 FR 21671) (FRL–6833–4), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 8E5026, 9E6049, 2E6359, 2E6365, 2E6377, and 2E6393]) by IR–4, New Jersey Agricultural Experiment Station, P. O. Box 231 Rutgers University, New Brunswick, NJ 08903. These notices included summaries of the petitions prepared by Novartis Crop Protection Inc., and Syngenta Crop Protection Inc., the registrants. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.516 be amended by establishing tolerances for residues of the fungicide fludioxonil, (4-(2,2-difluoro- 1,3-benzodioxol-4-yl)-1 *H*-pyrrole-3-carbonitrile), in or on bushberry subgroup at 2.0 part per million (ppm), caneberry subgroup at 5.0 ppm, juneberry at 2.0 ppm, lingonberry at 2.0 ppm, pistachio at 0.10 ppm, salal at 2.0 ppm, stone fruit group at 2.0 ppm, and watercress at 7.0 ppm. The petition for the stone fruit group was amended to propose a tolerance for fludioxonil at 5.0 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that '' there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of fludioxonil in or on the bushberry subgroup at 2.0 ppm, caneberry subgroup at 5.0 ppm, fruit, stone, group at 5.0 ppm, juneberry at 2.0 ppm, lingonberry at 2.0 ppm, pistachio at 0.10 ppm, salal at 2.0 ppm, and watercress at 7.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fludioxonil are discussed in Unit III.A. of the final rule on fludioxonil, which published in the **Federal Register** of December 29, 2000 (65 FR 82927) (FRL–6760–9). Additionally, recent toxicological studies (May 2002) concluded findings in conjunction to the toxicological profile noted in Unit III.A. of the final rule on fludioxonil (65 FR 82927). These studies are shown in Table 1:

TABLE 1.—CARCINOGENIC AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.4200b	Carcino-genicity rats	NOAEL = 590 mg/kg/day (M) and 715 mg/kg/day (F). LOAEL: 851 mg/kg/day (M) and 1,008 mg/kg/day (F) based on reduced survival (F), decreased body weights (M), bile duct hyperplasia (M) and severe nephropathy (both sexes). No evidence of carcinogenicity.
870.5395	*In vivo* Rat hepatocyte micronucleus assay	Male rats were orally dosed at 50, 250, and 1,250 mg/kg and hepatocytes were harvested. There was no evidence of a significant increase in micronucleated hepatocytes in treated groups in comparison to controls.
870.5550	Unscheduled DNA synthesis assay	There was no evidence that unscheduled DNA synthesis, as determined by nuclear silver grain counts, was induced in hepatocyte cultures obtained from male rats dosed at 2,500 or 5,000 mg/kg.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fludioxonil used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUDIOXONIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 1.0 mg/kg/day	Developmental Toxicity Study - rat Developmental LOAEL = 1,000 mg/kg/day based on increased incidence of fetuses and litters with dilated renal pelvis and dilated ureter
Chronic Dietary all populations	NOAEL= 3.3 mg/kg/day UF = 100 Chronic RfD = 0.03 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.03 mg/kg/day	1 year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Incidental Oral, Short-Term	NOAEL = 10 mg/kg/day	LOC for MOE = 100	Rabbit developmental study LOAEL = 100 mg/kg/day based on decreased weight gain during gestation
Incidental Oral, Intermediate-Term	NOAEL = 3.3 mg/kg/day	LOC for MOE = 100	1 year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Short-and Intermediate Term Dermal (1–30 days and 1–6 months) (Residential)	None	No systemic toxicity was seen at the limit dose (1,000 mg/kg/day) in the 28–day dermal toxicity study in rats	Endpoint was not selected
Long-Term (several months-lifetime) Dermal (Residential)	Oral study NOAEL = 3.3 mg/kg/day (dermal penetration = 40%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	1 year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Short-Term (1–30 Days) Inhalation (Residential)	Oral NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	Rabbit developmental study LOAEL = 100 mg/kg/day based on decreased weight gain during gestation
Intermediate-term (1 month – 6 months) Inhalation (Residential)	Oral NOAEL = 3.3 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	1 year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUDIOXONIL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-Term (several months-lifetime) Inhalation (Residential)	Oral NOAEL = 3.3 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	1 year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Cancer (oral, dermal, inhalation)	''Group D'' - not classifiable as to human carcinogenicity via relevant routes of exposure	Not applicable	There was no evidence of carcinogenicity in mice when tested up to the limited dose 7,000 ppm. There was no evidence of carcinogenicity in male rats, but there was a statistically significant increase, both trend and pairwise, of combined hepatocellular tumors in female rats. The pairwise increase for combined tumors was significant at p=0.03, which is not a strong indication of a positive effect. In addition, the increase in these tumors was within, but at the high end, of the historical controls.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.516) for the residues of fludioxonil, in or on a variety of raw agricultural commodities ranging from 0.01 ppm to 7.0 ppm as follows: cotton gin byproducts; flax, seed; forage, fodder, and straw of cereal grains; fruiting vegetables except cucurbits; grain, cereal; grape; grass, forage, fodder and hay, group; herbs and spices; leafy vegetables except brassica; leaves and roots of tuber vegetables; legume vegetables; non-grass animal feed; onion, dry bulb; onion, green; peanut hay; peanuts meat (hulls removed); rape forage; rape seed; safflower, seed; strawberry; sunflower, seed; undelinted cottonseed; vegetable, brassica, leafy, group; vegetable, bulb, group; vegetable, cucurbit, group; vegetable, legume, foliage; and vegetable, root and tuber, group. Risk assessments were conducted by EPA to assess dietary exposures from fludioxonil in food as follows:

i. *Acute Exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A conservative acute analysis was performed for the females 13–50 years old population subgroup using published and proposed tolerance levels, default concentration factors, and 100% CT assumptions for all commodities.

ii. *Chronic Exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic analysis was performed for the U.S. population, and other population subgroups using published and proposed tolerance levels, default concentration factors, and 100% CT assumptions for all commodities.

iii. *Cancer*. In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999), the Agency classified fludioxonil as a ''Group D'' - not classifiable as to human carcinogenicity.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fludioxonil in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of fludioxonil.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a

pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to fludioxonil they are further discussed in the aggregate risk sections in Unit II.E. of this document.

Fludioxonil is relatively immobile in soil (K_{oc} = 991 − 2440 ml/g). Laboratory adsorption-desorption studies suggest that the parent compound would be bound to soil and have a relatively low potential to leach to ground water and move in runoff to surface water. Degradates of fludioxonil are highly mobile and may enter both surface and ground water. Based on their low K_{oc} values, two of the three photolytic degradates identified in the laboratory studies (CGA–192155 and CGA–339833) are expected to be highly mobile in the environment. The third major photolytic degradate was found to be extremely unstable in the batch-equilibrium system; therefore, the mobility of this degradate could not be determined.

Tier I models, FIRST and SCI-GROW, were used to derive the surface water and ground water EECs, respectively. According to the proposed label information, the maximum application rate for fludioxonil is 4 lbs ai/Acre/year on turf (maximum single application rate of 0.675 lbs ai/Acre). Application to turf provided the high exposure scenario; therefore, the drinking water EECs were derived from the use on turf.

Based on the [FIRST] model the estimated environmental concentrations (EECs) of fludioxonil for acute and chronic exposures are estimated to be 132 parts per billion (ppb) and 49 ppb, respectively, for surface water.

Based on the SCI GROW model the estimated environmental concentration (EEC) of fludioxonil for ground water is estimated to be 0.11 ppb for both the acute and chronic exposures.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fludioxonil is currently registered for use on the following residential non-dietary sites: Based on the registered labels, fludioxonil is used as a protectant fungicide for control of certain diseases of turfgrass and certain foliar, stem and root diseases in ornamentals in residential and commercial landscapes. Medallion® (EPA Reg. No. 100–769) is registered for use on residential lawns and ornamentals. Medallion® is a wettable powder packaged in water-soluble packets, and the current label indicates that this product is ''for professional use only.'' As such, no residential handler (i.e., applicator) exposures are anticipated.

However, short- and intermediate-term dermal (adults and toddlers), and incidental ingestion (toddlers) post-application residential exposures are anticipated based on the use pattern for turfgrass applications detailed on the Medallion® label (specifies that the product be applied at 14-day application intervals, with an annual maximum rate of 2 lbs ai/A/yr, which equates to about 3 applications at the maximum per application rate. Also, fludioxonil has half-lives ranging from 95 to 440 days in thatch sod). A residential post-application dermal assessment was not performed since the risks from short- and intermediate-term dermal exposure are negligible. Short- and intermediate-term dermal endpoints were not selected due to the NOAEL of 1000 mg/kg/day (highest dose tested) in the 28-day dermal toxicity study in rats and also since there were no developmental concerns. EPA has concluded that there are no significant post-application exposures anticipated from treated landscape ornamentals. Therefore, the risk assessment was conducted using the following residential exposure assumption: post-residential lawn applications for toddler incidental ingestion.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether fludioxonil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fludioxonil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fludioxonil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for fludioxonil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X. The FQPA factor was reduced because the toxicology data base is complete; the developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required by the Agency because there was no evidence of neurotoxicity in the current toxicity data base; and the exposure assessment approach will not underestimate the potential dietary (food and water) and non-dietary exposures for infants and children resulting from the use of fludioxonil.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the

Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fludioxonil will occupy 0.7% of the aPAD for the females 13 years and older. Risk estimated for the general U.S. population subgroups were included in the representative population (females 13–50 years old). In addition, there is potential for acute dietary exposure to fludioxonil in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUDIOXONIL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	1.0	0.7	132	0.11	30,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fludioxonil from food will utilize 6.6% of the cPAD for the U.S. population; 32% of the cPAD for all infants (< 1 year old); 16% of the cPAD for children (1–6 years old); and 4.2% of the cPAD for females (13–50 years old). Based the use pattern, chronic residential exposure to residues of fludioxonil is not expected. In addition, there is potential for chronic dietary exposure to fludioxonil in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUDIOXONIL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.03	6.6	49	0.11	980
All infants (< 1 year old)	0.03	32	49	0.11	200
Children 1–6 years old	0.03	16	49	0.11	250
Females 13–50 years old	0.03	4.2	49	0.11	860

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fludioxonil is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fludioxonil. The label specifies that residential application is restricted to commercial handlers. Therefore, only post-application exposure is expected to result from the residential uses of fludioxonil. For adults, post-application exposures may result from dermal contact with treated turf. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. However, the Agency did not select short- dermal endpoints for fludioxonil. Therefore, the short-term aggregate risk for fludioxonil considers food, water, and residential non-dietary oral exposures (for toddlers).

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 5,000 for the U.S. population; 780 for all infants (< 1 year old); 820 for children (1–6 years old); and 7,900 for females (13–50 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of fludioxonil in ground and surface water.

After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FLUDIOXONIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	5,000	100	49	0.11	3,400
All infants (< 1 year old)	450	100	49	0.11	780
Children (1–6 years old)	570	100	49	0.11	820
Females (13–50 years old)	7,900	100	49	0.11	3,000

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fludioxonil is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for fludioxonil. The label specifies that the residential application of fludioxonil is restricted to commercial handlers. Therefore, only post-application exposure is expected to result from the residential uses of fludioxonil. For adults, post-application exposures may result from dermal contact with treated turf. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. However, the data did not indicate any adverse effects as a result of intermediate-term dermal exposure. Therefore, the intermediate-term aggregate risk for fludioxonil considers food, water, and residential non-dietary oral exposures (for toddlers).

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,700 for the U.S. population; 190 for all infants (< 1 year old); 270 for (children 1–6 years old); and 2,600 for females (13–50 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of fludioxonil in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO FLUDIOXONIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
U.S. population	1,700	100	49	0.11	980
All infants (< 1 year old)	190	100	49	0.11	130
Children (1–6 years old)	270	100	49	0.11	180
Females (13–50 years old)	2,600	100	49	0.11	860

5. *Aggregate cancer risk for U.S. population*. The Agency classified fludioxonil as (a ''Group D'') not classifiable as to human carcinogenicity based on the lack of evidence in mice when tested up to the limited dose 7,000 ppm. Additionally, there was no evidence of carcinogenicity in male rats, despite the statistically significant increase in both trend and pairwise of combined hepatocellular tumors in female rats. The pairwise increase for combined tumors was significant at p=0.03, which is not a strong indication of a positive effect. Furthermore, the increase in these tumors was within, but at the high end, of the historical controls.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fludioxonil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Based on the concurrent recovery values obtained from the crop field trial analyses and the previous successful petition method validation (PMV) conducted by EPA's Analytical Chemistry Branch (ACB), EPA concludes that HPLC method AG–597B is adequate to enforce the recommended tolerance levels for residues of fludioxonil *per se* in the bushberry subgroup, the caneberry subgroup, fruit, stone, group, juneberry, lingonberry, pistachio, salal, and watercress.

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center,

Environmental Protection Agency, 701 Mapes Road, Fort George G. Mead, MD 20755–5350; telephone number (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of fludioxonil in/on the bushberry subgroup, the caneberry subgroup, fruit, stone, group, juneberry, lingonberry, pistachio, salal, and watercress. Therefore, compatibility issues are not relevant to the proposed tolerances.

V. Conclusion

Therefore, tolerances are established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 *H*-pyrrole-3-carbonitrile), in or on bushberry subgroup at 2.0 ppm, caneberry subgroup at 5.0 ppm, fruit, stone, group at 5.0 ppm, juneberry at 2.0 ppm, lingonberry at 2.0 ppm, pistachio at 0.10 ppm, salal at 2.0 ppm, and watercress at 7.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0158 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 1, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0158, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not

contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 18, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.516 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) * * *

Commodity	Parts per million
Bushberry subgroup	2.0
Caneberry subgroup	5.0
* * * * *	
Fruit, stone, group	5.0
* * * * *	
Juneberry	2.0
* * * * *	
Lingonberry	2.0
* * * * *	
Pistachio	0.10
* * * * *	
Salal	2.0
* * * * *	
Watercress	7.0

* * * * *

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Modified Base (1-percent-annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Maps in effect for the listed communities prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive